REMARKS/ARGUMENTS

The examiner is thanked for entering the Rule 116 amendment filed May 2, 2006. The present amendment assumes prior entry of the claim amendments set forth in the Rule 116 amendment. The examiner is also thanked for withdrawing the rejection under section 112, second paragraph, as indicated in the advisory action mailed May 11, 2006.

In response to the anticipation rejections, claim 1 has now been amended to better clarify that applicant claims a finished pharmaceutical composition containing the recited active agents. As applicant understands the examiner's explanation, the anticipation rejection is based on (1) each active agent being administered to the same test animal (Cuillard reference) or placed into the same cell culture (Simard reference) , and (2) the claimed combination of active agents necessarily occuring in the test animal or culture media even if the references teach that one agent - - estrogen - - is to be avoided in the treatment of disease. However, the compounds administered to test animals in the cited reference, can intermix, at most, within the animal blood and tissues. When added to culture media, the two agents intermix only within the culture media.

To sustain a rejection under 35 U.S.C. § 102, the Examiner must show that each and every limitation of the claims is met by a single reference. Scripps Clinic & Research Foundation v. Genentech, Inc, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). There must be no difference between the claimed invention and the reference disclosure. Ibid. Among the limitations of the rejected claims that are neither disclosed nor suggested by these references is the limitation requiring "a pharmaceutically acceptable excipient, diluent or carrier." While such materials may have been added to the cell culture media or test animal, the result is not "pharmaceutically acceptable" in view of the animal blood or tissue, or culture media. To better describe that distinction, claim 1 has been further amended to recite that the pharmaceutical composition is "in finished form suitable for administering to a patient." Accordingly, it is urged that the anticipation rejections should be withdrawn.

The claims rejected for obviousness over the same Simard and Cuillard references are distinguishable by their requirement of "estrogen," which Simard and Cuillard teach should be avoided. While the examiner is correct that such "teaching away" is not relevant to the above anticipation rejection, "teaching away" is of critical importance on the issue of obviousness.

See MPEP 2144.08. All claims require "estrogen" while both the Simard reference and the Couillard reference teach against estrogen. Couillard notes (at abstract lines 6-7) that "Estrone caused a 10-fold increase in ZR-75-1 tumor area . . ." ZR-75-1 is defined as human mammary tumor. Likewise, Simard states that "estrogens play a predominant role in the development and growth of human breast cancer . . ." (Abstract, lines 1-2). In view of this teaching away from applicant's invention, it is urged that the obviousness rejections over Simard and Cuillard should be withdrawn.

Finally, claims 1-2, 13-19, 22-23 and 35-41 stand rejected as allegedly obvious over Luo, Barrett-Conner and Do Nascimento in view of Labrie WO 96/26201. However, Luo does not disclose an estrogen, Barrett-Conner does not test the presently-claimed SERMs on cholesterol, the Do Nascimento abstract expressly states that "[s]erum cholesterol levels were not altered by any of the treatments." Accordingly it is urged that there is no reason in these references to combine an estrogen with the SERM recited in the present claims. This deficiency of the prior art is not overcome by the cited Labrie reference which merely discusses certain antiestrogenic properties of the disclosed compounds. It is not seen how this discussion would motivate one of skill in the art to combine the disclosed compounds with the estrogens of either Do Nascimento or Barrett-Conner. Accordingly, it is urged that this obviousness rejection should be withdrawn.

It is urged that the application is now in condition for allowance. Issuance of a notice of allowance is solicited.

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail to Addressee (mail label #EV605026023US) in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: October 30, 2006

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Signature

October 30, 2006
Date of Signature

Respectfully submitted,

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